



Press release
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EMA transparency draft¹ is just window dressing HAI Europe, ISDB and MiEF make patient-friendly proposals

Health Action International (HAI) Europe, International Society of Drug Bulletins (ISDB) and Medicine in Europe Forum (MiEF) find that “EMA’s draft transparency policy” fails to restore citizens’ trust in its decision-making².

A situation that urgently needs to be improved. Despite claims to the contrary by the European Medicines Agency (EMA), the evidence demonstrates that, several years after the adoption European transparency regulations, the Agency is still highly secretive. Undue secrecy, particularly when it comes to pharmacovigilance data, delays the release of information that could have prevented adverse drug reactions and puts patients’ safety at risk.

The excuse of “commercial confidentiality” is used to justify excessive secrecy (in a report about rimonabant – formerly Acomplia^o - 65 pages of 68 pages were blacked out by EMA’s services³).

HAI Europe, ISDB and MiEF denounce unequal treatment among stakeholders, with an ‘industry first’ policy. They call for EMA to be funded through public money and be weaned from a fee-for-service relationship with pharmaceutical companies.

A weak policy compromises public health. HAI Europe, ISDB and MiEF stress citizens’ right to information held by EMA, particularly clinical data (raw and summarised), which are public property. Patients participate in clinical trials and expect benefits to the public through the advancement of science. Failure to make full research data available prevents the identification of adverse drug reactions by independent research teams, despite the fact that such independent studies have again shown their worth in terms of thousands of lives saved (i.e. identification of increased cardiovascular risks with rofecoxib (formerly Vioxx^o) and with rosiglitazone (Avandia^o)).

EMA gives a surprising list of “excuses” or “prerequisites” to justify the withholding of information: patronising arguments; willingness to protect “the decision-making process” from the public eye; a ‘lowest common denominator’ approach under the guise of “harmonisation” with the way national drug regulatory agencies work; over-caution; and exaggerated fear of upsetting commercial interests.

Concrete proposals for guarantying EMA’s accountability towards citizens.

HAI Europe, ISDB and MiEF call for “commercial confidentiality of proprietary information” to be redefined through a public debate. They advocate that all data with a bearing on human health, notably clinical data, should be excluded from the definition of “commercial confidentiality”, whether or not it affects sales. They also list a number of data that should be made available to the public without delay, and call for EMA’s expert committees to be held in public.

ISDB, HAI Europe and MiEF strongly call on EU policy makers to ensure that EMA is fully accountable to the public. Real transparency would certainly restore EU citizens’ confidence in EMA’s decisions. Transparency of drug regulatory agencies would also represent far better progress in terms of access to relevant information for the patients than EU Commission’s current proposals on ‘patient information’ aimed at legalising a disguised form of “direct-to-consumer advertising” in Europe.

References

- 1- “The EMA transparency policy – draft for public consultation” London, 19 June 2009 (Ref. EMA/232037/2009). (Deadline for answer 25th of September 2009). Available at: <http://www.emea.europa.eu/pdfs/human/transparency/23203709en.pdf>: 12 pages.
- 2- Full text of HAI Europe, ISDB and MiEF joint answer “EMA transparency policy falls short: a weak and irresponsible project”. Available at: http://prescrire.org/docus/JointAnswerEMEATranspPolicy_Sept2009.pdf: 38 pages
+ Annex A to this answer: Prescrire Editorial Staff “Legal obligations for transparency at the European Medicines Agency: Prescrire’s assessment over four years” *Prescrire International* 2009; **18** (103): 228-234. Available at: <http://www.prescrire.org/docus/transparency.pdf>.
- 3- Prescrire Editorial Staff “Censorship masquerading as transparency: the EMA assessment report on rimonabant” *Prescrire International* 2009; **18** (103): 231. Freely available at: <http://www.prescrire.org/docus/CensorshipEMEAEnglish.pdf>.

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HAI Europe. Health Action International (HAI) is an independent global network of health, consumer and development organisations working to increase access to essential medicines and improve rational use. More info: www.haiweb.org.



ISDB. International Society of Drug Bulletins (ISDB), founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 79 members in 40 countries around the world. More info: www.isdbweb.org. Contact : press@isdbweb.org.



MiEF. Medicines in Europe Forum (MiEF), launched in March 2002, covers 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing. Contact: europedumedicament@free.fr.